

Search Plan and Results

Question

[What is the relationship between the intake of vegetable protein, including soy protein and chronic disease? \(DGAC 2010\)](#)

[What is the relationship between the intake of vegetable protein and blood pressure among adults without hypertension? \(DGAC 2010\)](#)

[What is the relationship between the intake of soy protein and blood pressure among adults without hypertension? \(DGAC 2010\)](#)

[What is the relationship between the intake of soy protein and blood lipids among adults without hyperlipidemia? \(DGAC 2010\)](#)

[What is the relationship between the intake of soy protein and body weight? \(DGAC 2010\)](#)

Date Searched

9/19/09

Inclusion Criteria

- January 2000 to September 2009
- Prospective cohort studies on colorectal, breast and prostate cancers
- All study types for other health outcomes
- Human subjects
- English language
- International
- *Sample size*: Minimum of 10 subjects per study arm; preference for larger sizes, if available
- *Dropout rate*: Less than 20%; preference for smaller dropout rates
- *Ages*: Children two to 18 years; Adults 19 years and older
- *Populations*: Healthy, those with elevated chronic disease risk.

Exclusion Criteria

- Medical treatment or therapy
- Systematic reviews and meta-analyses on colorectal, breast and prostate cancers
- Narrative reviews
- Diseased subjects (already diagnosed with disease related to study purpose)
- Hospitalized patients
- Study population not from a developed country as defined by the Human Development Index (<http://hdr.undp.org/en/statistics/>)
- Animal studies
- In vitro studies

- Articles not peer reviewed (websites, magazine articles, Federal reports, etc.).

Search Terms: Search Vocabulary

("Diabetes Mellitus, Type 2"[mh] OR "metabolic syndrome X"[mh] OR "overweight"[mh] OR "hypertension"[mh] OR "dyslipidemias"[mh] OR "cardiovascular diseases"[mh:NoExp] OR "heart diseases"[mh] OR "Coronary Disease"[Mesh] OR "blood pressure"[mh] OR "chronic disease"[mh] OR obesity[mh] OR "Body Weights and Measures"[mh]) AND ("Soybean Proteins"[Mesh] OR "Vegetable Proteins"[Mesh])
Limit Eng/humans

("Soybean Proteins"[Mesh] OR "Vegetable Proteins"[Mesh]) AND ("Prostatic Neoplasms"[Mesh] OR "Breast Neoplasms"[Mesh] OR "Colorectal Neoplasms"[mesh])
clinical trials "Cohort Studies"[Mesh]

Electronic Databases

PubMed

Total hits from all electronic database searches: 343

Total articles identified to review from electronic databases: 86

Articles Identified Via Handsearch or Other Means

Hand search (eight studies):

Halton TL, Liu S, Manson JE, Hu FB. [Low-carbohydrate-diet score and risk of type 2 diabetes in women.](#) *Am J Clin Nutr.* 2008 Feb; 87 (2): 339-346. PMID: 18258623. (Hand search)

Halton TL, Willett WC, Liu S, Manson JE, Albert CM, Rexrode K, Hu FB. [Low-carbohydrate-diet score and the risk of coronary heart disease in women.](#) *N Engl J Med.* 2006 Nov 9; 355 (19): 1, 991-2, 002. PMID: 17093250. (Hand search)

Sluijs I, Beulens JW, van der A DL, Spijkerman AM, Grobbee DE, van der Schouw YT. [Dietary intake of total, animal, and vegetable protein and risk of type 2 diabetes in the European Prospective Investigation into Cancer and Nutrition \(EPIC\)-NL study.](#) *Diabetes Care.* 2010 Jan; 33(1): 43-48. Epub 2009 Oct 13. PMID: 19825820; PubMed Central PMCID: PMC2797984. (Hand search)

Song Y, Manson JE, Buring JE, Liu S. [A prospective study of red meat consumption and type 2 diabetes in middle-aged and elderly women: the women's health study.](#) *Diabetes Care.* 2004 Sep; 27 (9): 2, 108-2, 115. PMID: 15333470. (Hand search)

Stamler J, Liu K, Ruth KJ, Pryer J, Greenland P. [Eight-year blood pressure change in](#)

[middle-aged men: Relationship to multiple nutrients.](#) *Hypertension*. 2002 May; 39 (5): 1, 000-1, 006. PMID: 12019283. (Hand search)

Steffen LM, Kroenke CH, Yu X, Pereira MA, Slattery ML, Van Horn L, Gross MD, Jacobs DR Jr. [Associations of plant food, dairy product, and meat intakes with 15-year incidence of elevated blood pressure in young black and white adults: The Coronary Artery Risk Development in Young Adults \(CARDIA\) Study.](#) *Am J Clin Nutr*. 2005 Dec; 82 (6): 1, 169-1, 177; quiz 1363-4. PMID: 16332648. (Hand search)

Cope MB, Erdman JW Jr, Allison DB. [The potential role of soy foods in weight and adiposity reduction: an evidence-based review.](#) *Obes Rev*. 2008 May; 9 (3): 219-235. Review. PMID: 18419671. (Hand search)

Reynolds K, Chin A, Lees KA, Nguyen A, Bujnowski D, He J. [A meta-analysis of the effect of soy protein supplementation on serum lipids.](#) *Am J Cardiol*. 2006 Sep 1; 98 (5): 633-640. Epub 2006 Jul 12. PMID: 16923451. (Hand search)

Summary of Articles Identified to Review

Number of Primary Articles Identified: 19

Number of Review Articles Identified: 5

Total Number of Articles Identified: 24

Number of Articles Reviewed but Excluded: 70

List of Articles Included for Evidence Analysis

What is the relationship between the intake of vegetable protein, including soy protein and chronic disease?

Halton TL, Liu S, Manson JE, Hu FB. [Low-carbohydrate-diet score and risk of type 2 diabetes in women.](#) *Am J Clin Nutr*. 2008 Feb; 87 (2): 339-346. PMID: 18258623. (Hand search)

Kelemen LE, Kushi LH, Jacobs DR Jr, Cerhan JR. [Associations of dietary protein with disease and mortality in a prospective study of postmenopausal women.](#) *Am J Epidemiol*. 2005 Feb 1; 161 (3): 239-249. PMID: 15671256.

Lee SA, Shu XO, Li H, Yang G, Cai H, Wen W, Ji BT, Gao J, Gao YT, Zheng W. [Adolescent and adult soy food intake and breast cancer risk: Results from the Shanghai Women's Health Study.](#) *Am J Clin Nutr*. 2009 Jun; 89 (6): 1, 920-1, 926. Epub 2009 Apr 29. PMID: 19403632; PMCID: PMC2683002.

Sluijs I, Beulens JW, van der A DL, Spijkerman AM, Grobbee DE, van der Schouw YT. [Dietary intake of total, animal, and vegetable protein and risk of type 2 diabetes in the European Prospective Investigation into Cancer and Nutrition \(EPIC\)-NL study.](#) *Diabetes*

Care. 2010 Jan; 33(1): 43-48. Epub 2009 Oct 13. PMID: 19825820; PMCID: PMC2797984. (Hand search)

Song Y, Manson JE, Buring JE, Liu S. [A prospective study of red meat consumption and type 2 diabetes in middle-aged and elderly women: The women's health study.](#) *Diabetes Care.* 2004 Sep; 27 (9): 2, 108-2, 115. PMID: 15333470. (Hand search)

Nagata C. [Ecological study of the association between soy product intake and mortality from cancer and heart disease in Japan.](#) *Int J Epidemiol.* 2000 Oct; 29 (5): 832-836. PMID: 11034965.

What is the relationship between the intake of vegetable protein and blood pressure among adults without hypertension?

Stamler J, Liu K, Ruth KJ, Pryer J, Greenland P. [Eight-year blood pressure change in middle-aged men: Relationship to multiple nutrients.](#) *Hypertension.* 2002 May; 39 (5): 1, 000-1, 0006. PMID: 12019283. (Hand search)

Wang YF, Yancy WS Jr, Yu D, Champagne C, Appel LJ, Lin PH. [The relationship between dietary protein intake and blood pressure: results from the PREMIER study.](#) *J Hum Hypertens.* 2008 Nov; 22 (11): 745-754. Epub 2008 Jun 26. PMID: 18580887.

Steffen LM, Kroenke CH, Yu X, Pereira MA, Slattery ML, Van Horn L, Gross MD, Jacobs DR Jr. [Associations of plant food, dairy product, and meat intakes with 15-year incidence of elevated blood pressure in young black and white adults: The Coronary Artery Risk Development in Young Adults \(CARDIA\) Study.](#) *Am J Clin Nutr.* 2005 Dec; 82 (6): 1, 169-1, 177; quiz 1, 363-1, 364. PMID: 16332648. (Hand search)

Elliott P, Stamler J, Dyer AR, Appel L, Dennis B, Kesteloot H, Ueshima H, Okayama A, Chan Q, Garside DB, Zhou B. [Association between protein intake and blood pressure: The INTERMAP Study.](#) *Arch Intern Med.* 2006 Jan 9; 166 (1): 79-87. PMID: 16401814.

Umesawa M, Sato S, Imano H, Kitamura A, Shimamoto T, Yamagishi K, Tanigawa T, Iso H. [Relations between protein intake and blood pressure in Japanese men and women: The Circulatory Risk in Communities Study \(CIRCS\).](#) *Am J Clin Nutr.* 2009 Aug; 90 (2): 377-384. Epub 2009 Jun 10. PMID: 19515740.

What is the relationship between the intake of soy protein and blood pressure among adults without hypertension?

Teede HJ, Dalais FS, Kotsopoulos D, Liang YL, Davis S, McGrath BP. [Dietary soy has both beneficial and potentially adverse cardiovascular effects: A placebo-controlled study in men and postmenopausal women.](#) *J Clin Endocrinol Metab.* 2001 Jul; 86 (7): 3, 053-3, 060. PMID: 11443167.

Liao FH, Shieh MJ, Yang SC, Lin SH, Chien YW. [Effectiveness of a soy-based compared with a traditional low-calorie diet on weight loss and lipid levels in overweight adults.](#) *Nutrition.* 2007 Jul-Aug; 23 (7-8): 551-556. Epub 2007 Jun 15. PMID: 17574819.

Pan A, Franco OH, Ye J, Demark-Wahnefried W, Ye X, Yu Z, Li H, Lin X. [Soy protein intake has sex-specific effects on the risk of metabolic syndrome in middle-aged and elderly Chinese.](#) *J Nutr.* 2008 Dec; 138 (12): 2, 413-2, 421. PMID: 19022966.

What is the relationship between the intake of soy protein and body weight?

Systematic Review

Cope MB, Erdman JW Jr, Allison DB. [The potential role of soy foods in weight and adiposity reduction: An evidence-based review.](#) *Obes Rev.* 2008 May; 9 (3): 219-235. Review. PMID: 18419671. (Hand search)

Primary Citations

Liao FH, Shieh MJ, Yang SC, Lin SH, Chien YW. [Effectiveness of a soy-based compared with a traditional low-calorie diet on weight loss and lipid levels in overweight adults.](#) *Nutrition.* 2007 Jul-Aug; 23 (7-8): 551-556. Epub 2007 Jun 15. PMID: 17574819.

McVeigh BL, Dillingham BL, Lampe JW, Duncan AM. [Effect of soy protein varying in isoflavone content on serum lipids in healthy young men.](#) *Am J Clin Nutr.* 2006 Feb; 83 (2): 244-251. PMID: 16469981.

Pan A, Franco OH, Ye J, Demark-Wahnefried W, Ye X, Yu Z, Li H, Lin X. [Soy protein intake has sex-specific effects on the risk of metabolic syndrome in middle-aged and elderly Chinese.](#) *J Nutr.* 2008 Dec; 138 (12): 2, 413-2, 421. PMID: 19022966.

Systematic Reviews / Meta-Analyses

Yang G, Shu XO, Jin F, Zhang X, Li HL, Li Q, Gao YT, Zheng W. [Longitudinal study of soy food intake and blood pressure among middle-aged and elderly Chinese women.](#) *Am J Clin Nutr.* 2005 May; 81 (5): 1, 012-1, 017. PMID: 15883423.

Harland JI, Haffner TA. [Systematic review, meta-analysis and regression of randomized controlled trials reporting an association between an intake of circa 25g soy protein per day and blood cholesterol.](#) *Atherosclerosis.* 2008 Sep; 200 (1): 13-27. Epub 2008 Apr 15. Review. PMID: 18534601.

What is the relationship between the intake of soy protein and blood lipids among adults without hyperlipidemia?

Reynolds K, Chin A, Lees KA, Nguyen A, Bujnowski D, He J. [A meta-analysis of the effect of soy protein supplementation on serum lipids.](#) *Am J Cardiol.* 2006 Sep 1; 98 (5): 633-640. Epub 2006 Jul 12. PMID: 16923451. (Hand search)

Weggemans RM, Trautwein EA. [Relation between soy-associated isoflavones and LDL and HDL cholesterol concentrations in humans: A meta-analysis.](#) *Eur J Clin Nutr.* 2003 Aug; 57 (8): 940-946. PMID: 12879088.

Zhan S, Ho SC. [Meta-analysis of the effects of soy protein containing isoflavones on the lipid profile.](#) *Am J Clin Nutr.* 2005 Feb; 81 (2): 397-408. PMID: 15699227.

Primary Citations

Liao FH, Shieh MJ, Yang SC, Lin SH, Chien YW. [Effectiveness of a soy-based compared with a traditional low-calorie diet on weight loss and lipid levels in overweight adults.](#) *Nutrition.* 2007 Jul-Aug; 23 (7-8): 551-556. Epub 2007 Jun 15. PMID: 17574819.

Pan A, Franco OH, Ye J, Demark-Wahnefried W, Ye X, Yu Z, Li H, Lin X. [Soy protein intake has sex-specific effects on the risk of metabolic syndrome in middle-aged and elderly Chinese.](#) *J Nutr.* 2008 Dec; 138 (12): 2, 413-2, 421. PMID: 19022966.

He J, Gu D, Wu X, Chen J, Duan X, Chen J, Whelton PK. [Effect of soybean protein on blood pressure: A randomized, controlled trial.](#) *Ann Intern Med.* 2005 Jul 5; 143 (1):1-9. PMID: 15998749.

Alonso A, Beunza JJ, Bes-Rastrollo M, Pajares RM, Martínez-González MA. [Vegetable protein and fiber from cereal are inversely associated with the risk of hypertension in a Spanish cohort.](#) *Arch Med Res.* 2006 Aug; 37 (6): 778-786. PMID: 16824939.

Halton TL, Willett WC, Liu S, Manson JE, Albert CM, Rexrode K, Hu FB. [Low-carbohydrate-diet score and the risk of coronary heart disease in women.](#) *N Engl J Med.* 2006 Nov 9; 355 (19): 1, 991-2, 002. PMID: 17093250. (Hand search)

List of Excluded Articles with Reason

Article (A-K)	Reason for Exclusion
Ashton EL, Dalais FS, Ball MJ. Effect of meat replacement by tofu on CHD risk factors including copper induced LDL oxidation. <i>J Am Coll Nutr.</i> 2000 Nov-Dec; 19 (6): 761-767. PMID: 11194529.	Included in Zhan, 2005.
Azadbakht L, Kimiagar M, Mehrabi Y, Esmailzadeh A, Hu FB, Willett WC. Dietary soya intake alters plasma antioxidant status and lipid peroxidation in postmenopausal women with the metabolic syndrome. <i>Br J Nutr.</i> 2007 Oct; 98 (4): 807-813. Epub 2007 May 17. PMID: 17506931.	Participants diagnosed with metabolic syndrome.
Azadbakht L, Kimiagar M, Mehrabi Y, Esmailzadeh A, Hu FB, Willett WC. Soy consumption, markers of inflammation, and endothelial function: A cross-over study in postmenopausal women with the metabolic syndrome. <i>Diabetes Care.</i> 2007 Apr; 30 (4): 967-973. PMID: 17392557.	Participants diagnosed with metabolic syndrome.
Azadbakht L, Kimiagar M, Mehrabi Y, Esmailzadeh A, Padyab M, Hu FB, Willett WC. Soy inclusion in the diet improves features of the metabolic syndrome: a randomized crossover study in postmenopausal women. <i>Am J Clin Nutr.</i> 2007 Mar; 85 (3): 735-741. PMID: 17344494.	Participants diagnosed with metabolic syndrome.
Azadbakht L, Shakerhosseini R, Atabak S, Jamshidian M, Mehrabi Y, Esmail-Zadeh A. Beneficiary effect of dietary soy protein on lowering plasma levels of lipid and improving kidney function in type II diabetes with nephropathy. <i>Eur J Clin Nutr.</i> 2003 Oct; 57 (10): 1, 292-1, 294. PMID: 14506491.	Participants diagnosed with type 2 diabetes with nephropathy.

<p>Badger TM, Ronis MJ, Simmen RC, Simmen FA. Soy protein isolate and protection against cancer. <i>J Am Coll Nutr.</i> 2005 Apr; 24 (2): 146S-149S. PMID: 15798082.</p>	<p>Publication is a summary of a review presented at a professional meeting.</p>
<p>Blum A, Lang N, Vigder F, Israeli P, Gumanovsky M, Lupovitz S, Elgazi A, Peleg A, Ben-Ami M. Effects of soy protein on endothelium-dependent vasodilatation and lipid profile in postmenopausal women with mild hypercholesterolemia. <i>Clin Invest Med.</i> 2003 Feb; 26 (1): 20-26. PMID: 12659466.</p>	<p>Participants had mild hypercholesterolemia; included in Harland, 2008.</p>
<p>Brown BD, Thomas W, Hutchins A, Martini MC, Slavin JL. Types of dietary fat and soy minimally affect hormones and biomarkers associated with breast cancer risk in premenopausal women. <i>Nutr Cancer.</i> 2002; 43 (1): 22-30. PMID: 12467131.</p>	<p>Does not answer question: examined biomarkers associated with breast cancer, not incidence of breast cancer (not a prospective cohort study).</p>
<p>Chan YH, Lau KK, Yiu KH, Li SW, Chan HT, Tam S, Shu XO, Lau CP, Tse HF. Isoflavone intake in persons at high risk of cardiovascular events: Implications for vascular endothelial function and the carotid atherosclerotic burden. <i>Am J Clin Nutr.</i> 2007 Oct; 86 (4): 938-945. PMID: 17921368.</p>	<p>Participants (94%) had CAD or stroke; does not answer question: Outcomes were carotid intima-media thickness and flow-mediated dilation</p>
<p>Chen ST, Ferng SH, Yang CS, Peng SJ, Lee HR, Chen JR. Variable effects of soy protein on plasma lipids in hyperlipidemic and normolipidemic hemodialysis patients. <i>Am J Kidney Dis.</i> 2005 Dec; 46 (6): 1, 099-1, 106. PMID: 16310576.</p>	<p>Participants were hemodialysis patients.</p>
<p>Chiechi LM, Secreto G, Vimercati A, Greco P, Venturelli E, Pansini F, Fanelli M, Loizzi P, Selvaggi L. The effects of a soy rich diet on serum lipids: the Menfis randomized trial. <i>Maturitas.</i> 2002 Feb 26; 41 (2): 97-104. PMID: 11836040.</p>	<p>Dropout rate higher than inclusion criteria.</p>
<p>Cicero AF, Minardi M, Mirembe S, Pedro E, Gaddi A. Effects of a new low dose soy protein/beta-sitosterol association on plasma lipid levels and oxidation. <i>Eur J Nutr.</i> 2004 Oct; 43 (5): 319-322. Epub 2004 Jan 26. PMID: 15309453.</p>	<p>Participants were hypercholesterolemic; does not answer question: Tested a formulation of soy protein with added beta-sitosterol.</p>
<p>Cuevas AM, Irribarra VL, Castillo OA, Yañez MD, Germain AM. Isolated soy protein improves endothelial function in postmenopausal hypercholesterolemic women. <i>Eur J Clin Nutr.</i> 2003 Aug; 57 (8): 889-894. PMID: 12879082.</p>	<p>Participants were hypercholesterolemic.</p>

<p>Cupisti A, D'Alessandro C, Ghiadoni L, Morelli E, Panichi V, Barsotti G. Effect of a soy protein diet on serum lipids of renal transplant patients. <i>J Ren Nutr.</i> 2004 Jan; 14 (1): 31-35. PMID: 14740328.</p>	<p>Participants had renal transplantation.</p>
<p>Desroches S, Mauger JF, Ausman LM, Lichtenstein AH, Lamarche B. Soy protein favorably affects LDL size independently of isoflavones in hypercholesterolemic men and women. <i>J Nutr.</i> 2004 Mar; 134 (3): 574-579. PMID: 14988449.</p>	<p>Participants were hypercholesterolemic.</p>
<p>Dewell A, Weidner G, Sumner MD, Barnard RJ, Marlin RO, Daubenmier JJ, Chi C, Carroll PR, Ornish D. Relationship of dietary protein and soy isoflavones to serum IGF-1 and IGF binding proteins in the Prostate Cancer Lifestyle Trial. <i>Nutr Cancer.</i> 2007; 58 (1): 35-42. PMID: 17571965.</p>	<p>Participants were diagnosed with prostate cancer.</p>
<p>Dillingham BL, McVeigh BL, Lampe JW, Duncan AM. Soy protein isolates of varying isoflavone content exert minor effects on serum reproductive hormones in healthy young men. <i>J Nutr.</i> 2005 Mar; 135 (3): 584-591. PMID: 15735098.</p>	<p>Does not answer question: Examined soy protein intake on reproductive hormones.</p>
<p>Engelman HM, Alekel DL, Hanson LN, Kanthasamy AG, Reddy MB. Blood lipid and oxidative stress responses to soy protein with isoflavones and phytic acid in postmenopausal women. <i>Am J Clin Nutr.</i> 2005 Mar; 81 (3): 590-596. PMID: 15755827.</p>	<p>Does not answer question: Examined impact of soy protein components (isoflavones and phytate) on blood lipids and oxidative stress.</p>
<p>Gardner CD, Messina M, Kiazand A, Morris JL, Franke AA. Effect of two types of soy milk and dairy milk on plasma lipids in hypercholesterolemic adults: A randomized trial. <i>J Am Coll Nutr.</i> 2007 Dec; 26 (6): 669-677. PMID: 18187432.</p>	<p>Participants were hypercholesterolemic; included in Harland, 2008.</p>
<p>Gardner CD, Newell KA, Cherin R, Haskell WL. The effect of soy protein with or without isoflavones relative to milk protein on plasma lipids in hypercholesterolemic postmenopausal women. <i>Am J Clin Nutr.</i> 2001 Apr; 73 (4): 728-735. PMID: 11273847.</p>	<p>Participants were hypercholesterolemic; included in Weggemans, 2003.</p>
<p>Genovese MI, Lajolo FM. Isoflavones in soy-based foods consumed in Brazil: Levels, distribution, and estimated intake. <i>J Agric Food Chem.</i> 2002 Oct 9; 50 (21): 987-5, 993. PMID: 12358470.</p>	<p>Does not include health outcomes in analyses.</p>

<p>Giampietro PG, Bruno G, Furcolo G, Casati A, Brunetti E, Spadoni GL, Galli E. Soy protein formulas in children: No hormonal effects in long-term feeding. <i>J Pediatr Endocrinol Metab.</i> 2004 Feb;17 (2): 191-196. PMID: 15055353.</p>	<p>Does not answer question: Examined hormonal and metabolic effects of long-term soy protein formula feeding.</p>
<p>Goldin BR, Brauner E, Adlercreutz H, Ausman LM, Lichtenstein AH. Hormonal response to diets high in soy or animal protein without and with isoflavones in moderately hypercholesterolemic subjects. <i>Nutr Cancer.</i> 2005; 51 (1): 1-6. PMID: 15749623.</p>	<p>Participants were hypercholesterolemic; does not answer question: Examined hormonal response to diets high in soy or animal protein.</p>
<p>Grainger EM, Schwartz SJ, Wang S, Unlu NZ, Boileau TW, Ferketich AK, Monk JP, Gong MC, Bahnson RR, DeGroff VL, Clinton SK. A combination of tomato and soy products for men with recurring prostate cancer and rising prostate specific antigen. <i>Nutr Cancer.</i> 2008; 60 (2): 145-154. PMID: 18444145.</p>	<p>Participants diagnosed with prostate cancer.</p>
<p>Greany KA, Nettleton JA, Wangen KE, Thomas W, Kurzer MS. Consumption of isoflavone-rich soy protein does not alter homocysteine or markers of inflammation in postmenopausal women. <i>Eur J Clin Nutr.</i> 2008 Dec; 62 (12): 1, 419-1, 425. Epub 2007 Sep 5. PMID: 17805230.</p>	<p>Does not answer question: Does not examine outcome of interest (examines homocysteine, C-reactive protein and adhesion molecules).</p>
<p>Greany KA, Nettleton JA, Wangen KE, Thomas W, Kurzer MS. Probiotic consumption does not enhance the cholesterol-lowering effect of soy in postmenopausal women. <i>J Nutr.</i> 2004 Dec; 134 (12): 3, 277-3, 283. PubMed PMID: 15570025.</p>	<p>Participants were hypercholesterolemic; included in Harland, 2008.</p>
<p>Hamilton-Reeves JM, Rebello SA, Thomas W, Kurzer MS, Slaton JW. Effects of soy protein isolate consumption on prostate cancer biomarkers in men with HGPIN, ASAP, and low-grade prostate cancer. <i>Nutr Cancer.</i> 2008; 60 (1): 7-13. PMID: 18444130.</p>	<p>Not a prospective cohort study examining incidence of prostate cancer. Outcomes were prostate cancer biomarkers.</p>
<p>Hamilton-Reeves JM, Rebello SA, Thomas W, Slaton JW, Kurzer MS. Soy protein isolate increases urinary estrogens and the ratio of 2:16alpha-hydroxyestrone in men at high risk of prostate cancer. <i>J Nutr.</i> 2007 Oct; 137 (10): 2, 258-2, 263. PMID: 17885008.</p>	<p>Not a prospective cohort study examining incidence of prostate cancer. Outcomes were prostate cancer biomarkers.</p>

<p>Hamilton-Reeves JM, Rebello SA, Thomas W, Slaton JW, Kurzer MS. Isoflavone-rich soy protein isolate suppresses androgen receptor expression without altering estrogen receptor-beta expression or serum hormonal profiles in men at high risk of prostate cancer. <i>J Nutr.</i> 2007 Jul; 137 (7): 1, 769-1, 775. PMID: 17585029.</p>	<p>Not a prospective cohort study examining incidence of prostate cancer. Outcomes were prostate cancer biomarkers.</p>
<p>Harrison RA, Sagara M, Rajpura A, Armitage L, Birt N, Birt CA, Yamori Y. Can foods with added soya-protein or fish-oil reduce risk factors for coronary disease? A factorial randomised controlled trial. <i>Nutr Metab Cardiovasc Dis.</i> 2004 Dec; 14 (6): 344-350. PMID: 15853118.</p>	<p>Participants had elevated total cholesterol or blood pressure.</p>
<p>Hartman JW, Tang JE, Wilkinson SB, Tarnopolsky MA, Lawrence RL, Fullerton AV, Phillips SM. Consumption of fat-free fluid milk after resistance exercise promotes greater lean mass accretion than does consumption of soy or carbohydrate in young, novice, male weightlifters. <i>Am J Clin Nutr.</i> 2007 Aug; 86 (2): 373-381. PMID: 17684208.</p>	<p>Does not answer question: Does not examine relationship between vegetable protein and health (examined consumption of various isocaloric drinks on lean mass accretion following resistance training).</p>
<p>Hoie LH, Guldstrand M, Sjöholm A, Graubaum HJ, Gruenwald J, Zunft HJ, Lueder W. Cholesterol-lowering effects of a new isolated soy protein with high levels of nondenaturated protein in hypercholesterolemic patients. <i>Adv Ther.</i> 2007 Mar-Apr; 24 (2): 439-447. PMID: 17565935.</p>	<p>Participants were hypercholesterolemic; included in Harland, 2008.</p>
<p>Hoie LH, Morgenstern EC, Gruenwald J, Graubaum HJ, Busch R, Lüder W, Zunft HJ. A double-blind placebo-controlled clinical trial compares the cholesterol-lowering effects of two different soy protein preparations in hypercholesterolemic subjects. <i>Eur J Nutr.</i> 2005 Mar; 44 (2): 65-71. Epub 2004 Apr 5. PMID: 15309422.</p>	<p>Participants were hypercholesterolemic; included in Harland, 2008.</p>
<p>Hori G, Wang MF, Chan YC, Komatsu T, Wong Y, Chen TH, Yamamoto K, Nagaoka S, Yamamoto S. Soy protein hydrolyzate with bound phospholipids reduces serum cholesterol levels in hypercholesterolemic adult male volunteers. <i>Biosci Biotechnol Biochem.</i> 2001 Jan; 65 (1): 72-78. PMID: 11272848.</p>	<p>Participants were hypercholesterolemic.</p>

<p>Jenkins DJ, Kendall CW, Jackson CJ, Connelly PW, Parker T, Faulkner D, Vidgen E, Cunnane SC, Leiter LA, Josse RG. Effects of high- and low-isoflavone soyfoods on blood lipids, oxidized LDL, homocysteine, and blood pressure in hyperlipidemic men and women. <i>Am J Clin Nutr.</i> 2002 Aug; 76 (2): 365-372. PMID: 12145008.</p>	<p>Participants were hyperlipidemic; included in Weggemans, 2003.</p>
<p>Jenkins DJ, Kendall CW, D'Costa MA, Jackson CJ, Vidgen E, Singer W, Silverman JA, Koumbridis G, Honey J, Rao AV, Fleshner N, Klotz L. Soy consumption and phytoestrogens: effect on serum prostate specific antigen when blood lipids and oxidized low-density lipoprotein are reduced in hyperlipidemic men. <i>J Urol.</i> 2003 Feb; 169 (2): 507-511. PMID: 12544298.</p>	<p>Participants were hyperlipidemic.</p>
<p>Jenkins DJ, Kendall CW, Garsetti M, Rosenberg-Zand RS, Jackson CJ, Agarwal S, Rao AV, Diamandis EP, Parker T, Faulkner D, Vuksan V, Vidgen E. Effect of soy protein foods on low-density lipoprotein oxidation and ex vivo sex hormone receptor activity: A controlled crossover trial. <i>Metabolism.</i> 2000 Apr; 49 (4): 537-543. PMID: 10778882.</p>	<p>Participants were hyperlipidemic; included in Harland, 2008.</p>
<p>Jenkins DJ, Wong JM, Kendall CW, Esfahani A, Ng VW, Leong TC, Faulkner DA, Vidgen E, Greaves KA, Paul G, Singer W. The effect of a plant-based low-carbohydrate ("Eco-Atkins") diet on body weight and blood lipid concentrations in hyperlipidemic subjects. <i>Arch Intern Med.</i> 2009 Jun 8; 169 (11): 1, 046-1, 054. Erratum in: <i>Arch Intern Med.</i> 2009 Sep 14; 169 (16): 1, 490. PMID: 19506174.</p>	<p>Participants were hyperlipidemic.</p>
<p>Jenkins DJ, Kendall CW, Faulkner DA, Kemp T, Marchie A, Nguyen TH, Wong JM, de Souza R, Emam A, Vidgen E, Trautwein EA, Lapsley KG, Josse RG, Leiter LA, Singer W. Long-term effects of a plant-based dietary portfolio of cholesterol-lowering foods on blood pressure. <i>Eur J Clin Nutr.</i> 2008 Jun; 62 (6): 781-788. Epub 2007 Apr 25. PMID: 17457340.</p>	<p>Participants were hyperlipidemic.</p>
<p>Jenkins DJ, Kendall CW, Marchie A, Faulkner D, Vidgen E, Lapsley KG, Trautwein EA, Parker TL, Josse RG, Leiter LA, Connelly PW. The effect of combining plant sterols, soy protein, viscous fibers, and almonds in treating hypercholesterolemia. <i>Metabolism.</i> 2003 Nov; 52</p>	<p>Participants were hypercholesterolemic; included in Cope, 2008.</p>

(11): 1, 478-1, 483. PMID: 14624410.	
Jenkins DJ, Kendall CW, Vidgen E, Mehling CC, Parker T, Seyler H, Faulkner D, Garsetti M, Griffin LC, Agarwal S, Rao AV, Cunnane SC, Ryan MA, Connelly PW, Leiter LA, Vuksan V, Josse R. The effect on serum lipids and oxidized low-density lipoprotein of supplementing self-selected low-fat diets with soluble-fiber, soy and vegetable protein foods. <i>Metabolism</i> . 2000 Jan; 49 (1): 67-72. PMID: 10647066.	Participants were hyperlipidemic.
Jenkins DJ, Kendall CW, Faulkner D, Vidgen E, Trautwein EA, Parker TL, Marchie A, Koumbridis G, Lapsley KG, Josse RG, Leiter LA, Connelly PW. A dietary portfolio approach to cholesterol reduction: combined effects of plant sterols, vegetable proteins, and viscous fibers in hypercholesterolemia. <i>Metabolism</i> . 2002 Dec; 51 (12): 1, 596-1, 604. PMID: 12489074.	Participants were hypercholesterolemic.
Jones PJ, Raeini-Sarjaz M, Jenkins DJ, Kendall CW, Vidgen E, Trautwein EA, Lapsley KG, Marchie A, Cunnane SC, Connelly PW. Effects of a diet high in plant sterols, vegetable proteins, and viscous fibers (dietary portfolio) on circulating sterol levels and red cell fragility in hypercholesterolemic subjects. <i>Lipids</i> . 2005 Feb; 40 (2): 169-174. PMID: 15884765.	Participants were hypercholesterolemic.
Kreijkamp-Kaspers S, Kok L, Bots ML, Grobbee DE, Lampe JW, van der Schouw YT. Randomized controlled trial of the effects of soy protein containing isoflavones on vascular function in postmenopausal women. <i>Am J Clin Nutr</i> . 2005 Jan; 81 (1): 189-195. PMID: 15640479.	Dropout rate higher than inclusion criteria.

Article (L-R)	Reason for Exclusion
Lichtenstein AH, Jalbert SM, Adlercreutz H, Goldin BR, Rasmussen H, Schaefer EJ, Ausman LM. Lipoprotein response to diets high in soy or animal protein with and without isoflavones in moderately hypercholesterolemic subjects. <i>Arterioscler Thromb Vasc Biol</i> . 2002 Nov 1; 22 (11): 1, 852-1, 858. PMID: 12426215.	Participants were hypercholesterolemic; included in Reynolds, 2006.

<p>Luiking YC, Deutz NE, Jäkel M, Soeters PB. Casein and soy protein meals differentially affect whole-body and splanchnic protein metabolism in healthy humans. <i>J Nutr.</i> 2005 May; 135 (5): 1, 080-1, 087. PMID: 15867285.</p>	<p>Does not answer question: study examined protein metabolism, not relationship between protein and selected health outcomes.</p>
<p>Ma Y, Chiriboga D, Olendzki BC, Nicolosi R, Merriam PA, Ockene IS. Effect of soy protein containing isoflavones on blood lipids in moderately hypercholesterolemic adults: A randomized controlled trial. <i>J Am Coll Nutr.</i> 2005 Aug; 24 (4): 275-285. PMID: 16093405.</p>	<p>Participants were hypercholesterolemic.</p>
<p>Mackey R, Ekangaki A, Eden JA. The effects of soy protein in women and men with elevated plasma lipids. <i>Biofactors.</i> 2000; 12 (1-4): 251-257. PMID: 11216493.</p>	<p>Participants were hyperlipidemic.</p>
<p>Maskarinec G. Soy foods for breast cancer survivors and women at high risk for breast cancer? <i>J Am Diet Assoc.</i> 2005 Oct; 105 (10): 1, 524-1, 528. PMID: 16183350.</p>	<p>Publication is Commentary.</p>
<p>Matthan NR, Jalbert SM, Ausman LM, Kuvin JT, Karas RH, Lichtenstein AH. Effect of soy protein from differently processed products on cardiovascular disease risk factors and vascular endothelial function in hypercholesterolemic subjects. <i>Am J Clin Nutr.</i> 2007 Apr; 85 (4): 960-966. Erratum in: <i>Am J Clin Nutr.</i> 2007 Aug; 86 (2): 525. PMID: 17413093.</p>	<p>Participants were hypercholesterolemic; included in Harland, 2008.</p>
<p>McVeigh BL, Dillingham BL, Lampe JW, Duncan AM. Effect of soy protein varying in isoflavone content on serum lipids in healthy young men. <i>Am J Clin Nutr.</i> 2006 Feb; 83 (2): 244-251. PMID: 16469981.</p>	<p>**Included in body weight review, but excluded from cholesterol review because included in Harland, 2008.</p>
<p>Merritt JC. Metabolic syndrome: soybean foods and serum lipids. <i>J Natl Med Assoc.</i> 2004 Aug; 96 (8): 1, 032-1, 041. PubMed PMID: 15303407; Central PMCID: PMC2568482.</p>	<p>Study design is narrative review.</p>
<p>Möllsten AV, Dahlquist GG, Stattin EL, Rudberg S. Higher intakes of fish protein are related to a lower risk of microalbuminuria in young Swedish type 1 diabetic patients. <i>Diabetes Care.</i> 2001 May; 24 (5): 805-810. PMID: 11347734.</p>	<p>Participants were diagnosed with type 1 diabetes.</p>

<p>Nagata C, Shimizu H, Takami R, Hayashi M, Takeda N, Yasuda K. Association of blood pressure with intake of soy products and other food groups in Japanese men and women. <i>Prev Med.</i> 2003 Jun; 36 (6): 692-697. PMID: 12744912.</p>	<p>Does not answer question: Examined soy food intake, not soy protein.</p>
<p>Puska P, Korpelainen V, Høie LH, Skovlund E, Smerud KT. Isolated soya protein with standardized levels of isoflavones, cotyledon soya fibres and soya phospholipids improves plasma lipids in hypercholesterolaemia: A double-blind, placebo-controlled trial of a yoghurt formulation. <i>Br J Nutr.</i> 2004 Mar; 91 (3): 393-401. PMID: 15005825.</p>	<p>Does not answer question: Examined yogurt formulation containing isolated soya protein, isoflavones, cotyledon soya fibers and soya phospholipids.</p>

Article (S-Z)	Reason for Exclusion
<p>Sacks FM, Lichtenstein A, Van Horn L, Harris W, Kris-Etherton P, Winston M; American Heart Association Nutrition Committee. Soy protein, isoflavones, and cardiovascular health: An American Heart Association Science Advisory for professionals from the Nutrition Committee. <i>Circulation.</i> 2006 Feb 21; 113 (7): 1, 034-1, 044. Epub 2006 Jan 17. PMID: 16418439.</p>	<p>Publication is AHA Science Advisory; reference list was reviewed.</p>
<p>Sagara M, Kanda T, NJelekera M, Teramoto T, Armitage L, Birt N, Birt C, Yamori Y. Effects of dietary intake of soy protein and isoflavones on cardiovascular disease risk factors in high risk, middle-aged men in Scotland. <i>J Am Coll Nutr.</i> 2004 Feb; 23 (1): 85-91. PMID: 14963058.</p>	<p>Included in Harland, 2008.</p>
<p>Sanders TA, Dean TS, Grainger D, Miller GJ, Wiseman H. Moderate intakes of intact soy protein rich in isoflavones compared with ethanol-extracted soy protein increase HDL but do not influence transforming growth factor beta(1) concentrations and hemostatic risk factors for coronary heart disease in healthy subjects. <i>Am J Clin Nutr.</i> 2002 Aug; 76 (2): 373-377. PMID: 12145009.</p>	<p>Does not answer question; design of the study does not allow for comparison between diets with and without soy protein. The study addresses the impact of isoflavones from soy on CHD risk.</p>

<p>Shahbazian H, Reza A, Javad S, Heshmatollah S, Mahmood L, Ali A, Hosain HM. Beneficial effects of soy protein isoflavones on lipid and blood glucose concentrations in type 2 diabetic subjects. <i>Saudi Med J.</i> 2007 Apr; 28 (4): 652-654. PMID: 17457503.</p>	<p>Participants diagnosed with type 2 diabetes.</p>
<p>Sirtori CR, Eberini I, Arnoldi A. Hypocholesterolaemic effects of soya proteins: Results of recent studies are predictable from the Anderson meta-analysis data. <i>Br J Nutr.</i> 2007 May; 97 (5): 816-822. Review. PMID: 17408521.</p>	<p>Not a systematic review or original research study (examines previous research using a predictive model).</p>
<p>Spence LA, Lipscomb ER, Cadogan J, Martin B, Wastney ME, Peacock M, Weaver CM. The effect of soy protein and soy isoflavones on calcium metabolism in postmenopausal women: A randomized crossover study. <i>Am J Clin Nutr.</i> 2005 Apr; 81 (4): 916-922. PMID: 15817872.</p>	<p>Does not answer question: Outcome was calcium metabolism, not selected health outcome.</p>
<p>St-Onge MP, Claps N, Wolper C, Heymsfield SB. Supplementation with soy-protein-rich foods does not enhance weight loss. <i>J Am Diet Assoc.</i> 2007 Mar; 107 (3): 500-505. PMID: 17324670.</p>	<p>Dropout rate higher than inclusion criteria.</p>
<p>Taku K, Umegaki K, Sato Y, Taki Y, Endoh K, Watanabe S. Soy isoflavones lower serum total and LDL cholesterol in humans: A meta-analysis of 11 randomized controlled trials. <i>Am J Clin Nutr.</i> 2007 Apr; 85 (4): 1, 148-1, 156. Erratum in: <i>Am J Clin Nutr.</i> 2007 Sep; 86 (3): 809. PMID: 17413118.</p>	<p>Does not answer question: Examined soy isoflavones, not soy protein.</p>
<p>Teede HJ, Dalais FS, Kotsopoulos D, Liang YL, Davis S, McGrath BP. Dietary soy has both beneficial and potentially adverse cardiovascular effects: A placebo-controlled study in men and postmenopausal women. <i>J Clin Endocrinol Metab.</i> 2001 Jul; 86 (7): 3, 053-3, 060. PMID: 11443167.</p>	<p>** Included in blood pressure review but excluded from cholesterol review because included in Harland, 2008 and Weggemans, 2003.</p>
<p>Teede HJ, Giannopoulos D, Dalais FS, Hodgson J, McGrath BP. Randomized, controlled, cross-over trial of soy protein with isoflavones on blood pressure and arterial function in hypertensive subjects. <i>J Am Coll Nutr.</i> 2006 Dec; 25 (6): 533-540. PMID: 17229901.</p>	<p>Participants were hypertensive.</p>
<p>Tonstad S, Smerud K, Høie L. A comparison of the effects of two doses of soy protein or casein on serum lipids, serum lipoproteins and plasma total homocysteine in hypercholesterolemic subjects. <i>Am J Clin Nutr.</i> 2002 Jul; 76 (1): 78-84.</p>	<p>Participants were hypercholesterolemic.</p>

PMID: 12081819.	
Trock BJ, Hilakivi-Clarke L, Clarke R. Meta-analysis of soy intake and breast cancer risk . <i>J Natl Cancer Inst</i> . 2006 Apr 5; 98 (7): 459-471. PMID: 16595782.	Studies included in meta-analysis were excluded based on SC criteria; no prospective cohort studies with soy protein included in review.
Wang Y, Jones PJ, Ausman LM, Lichtenstein AH. Soy protein reduces triglyceride levels and triglyceride fatty acid fractional synthesis rate in hypercholesterolemic subjects . <i>Atherosclerosis</i> . 2004 Apr; 173 (2): 269-275. PMID: 15064101.	Participants were hypercholesterolemic.
Wangen KE, Duncan AM, Xu X, Kurzer MS. Soy isoflavones improve plasma lipids in normocholesterolemic and mildly hypercholesterolemic postmenopausal women . <i>Am J Clin Nutr</i> . 2001 Feb; 73 (2): 225-231. PMID: 11157317.	Included in Zhan, 2005.
Weghuber D, Widhalm K. Effect of three-month treatment of children and adolescents with familial and polygenic hypercholesterolaemia with a soya-substituted diet . <i>Br J Nutr</i> . 2008 Feb; 99 (2): 281-286. Epub 2007 Aug 13. PMID: 17697400.	Participants were children and adolescents with familial or polygenic hypercholesterolemia.
Xu X, Duncan AM, Wangen KE, Kurzer MS. Soy consumption alters endogenous estrogen metabolism in postmenopausal women . <i>Cancer Epidemiol Biomarkers Prev</i> . 2000 Aug; 9 (8): 781-786. PMID: 10952094.	Does not answer question: Examines soy consumption and estrogen metabolism.
Yildirim A, Tokgozoglu SL, Oduncu T, Oto A, Haznedaroglu I, Akinci D, Koksali G, Sade E, Kirazli S, Kes S. Soy protein diet significantly improves endothelial function and lipid parameters . <i>Clin Cardiol</i> . 2001 Nov; 24 (11): 711-716. PMID: 11714128.	Participants were hypercholesterolemic.